DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUG FOR VETERINARY USE

3261. Adulteration and misbranding of P-V-F-M. U. S. v. 69 Bottles * * *. (F. D. C. No. 29719. Sample No. 85305-K.)

LIBEL FILED: September 7, 1950, District of South Dakota.

ALLEGED SHIPMENT: During September or October 1949, by Dr. I. W. Martin, from Sibley, Iowa.

PRODUCT: 69 250-cc. bottles of *P-V-F-M* at Sioux Falls, S. Dak. Analysis showed that the product contained materially more sulfanilamide and materially less tyrothricin than declared upon the label. The article was strongly alkaline. It completely inactivated penicillin G almost immediately on contact.

LABEL, IN PART: "P-V-F-M A Vehicle for incorporating Penicillin G for treating Mastitis due to Streptococcus Agalactiae * * Ingredients Sulfanilamide, 3 grs./fl. oz. Tyrothricin 4.7 mgms./fl. oz. Water * * * Manufactured by Nelson Laboratories, Sioux Falls, South Dakota."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "A Vehicle for incorporating Penicillin G" was misleading since the article inactivated penicillin G almost immediately upon contact, and, further, the label statement "Manufactured By Nelson Laboratories, Sioux Falls, South Dakota" was false and misleading since the article was not manufactured by Nelson Laboratories, nor at Sioux Falls, S. Dak.; and, Section 502 (j), the article by reason of its alkalinity was dangerous to health when used as directed on the bottle label, namely, "* * inject the entire contents of this bottle into one infected quarter through the teat canal. It may be * * * left in the quarter of dry/cows."

Disposition: October 17, 1950. Default decree of condemnation and destruction.

RUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3262. Misbranding of Dexedrine Sulfate tablets. U. S. v. Mark Halsey Drug Stores, William C. Reynolds, Arthur D. Purswell, and James C. Richards. Pleas of nolo contendere. Mark Halsey Drug Stores fined \$500; William C. Reynolds, Arthur D. Purswell, and James C. Richards each fined \$100. (F. D. C. No. 29431. Sample Nos. 68012–K, 68015–K, 68016–K, 68095–K.)

Information Filed: July 15, 1950, Northern District of Texas, against Mark Halsey Drug Stores, a partnership, Lubbock, Tex., and William C. Reynolds, Arthur D. Purswell, and James C. Richards. The Mark Halsey Drug Stores was charged with causing the sales in each of the 4 counts of the information; William C. Reynolds was charged with the sale in count 1; Arthur D. Purswell was charged with the sale in counts 2 and 4; and James C. Richards was charged with the sale in count 3.

INTERSTATE SHIPMENT: On or about October 11, 1949, from Philadelphia, Pa., into the State of Texas, of quantities of Dexedrine Sulfate tablets.

ALLEGED VIOLATION: On or about November 16, 18, 19, and 21, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants repacked and caused to be repacked a number of tablets of the drug, and sold and caused the tablets to be sold without a prescription, which acts of the defendants resulted in the drug being misbranded. Portions of the repackaged *Dexedrine Sulfate tablets* were labeled in part: "Mark Halsey Drug Store No. 2 College and Broadway Dial 4656 Lubbock, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (b) (1), portions of the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the repackaged drug bore no labeling containing directions for use.

DISPOSITION: September 27, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$500 against the partnership on count 1 and suspended the imposition of sentence against the partnership on the remaining 3 counts; William C. Reynolds was fined \$100 on count 1; Arthur D. Purswell was fined \$100 on count 2, was given a suspended sentence, and was placed on probation for 1 year on count 4; and James C. Richards was fined \$100 on count 3.

3263 Misbranding of diethylstilbestrol tablets, Dexedrine Sulfate tablets, and sulfadiazine and sodium bicarbonate tablets. U. S. v. Evans Drug Co., Inc., and Robert H. Wyatt, Walter M. Boyett, and Ralph H. Duncan. Pleas of nolo contendere by all defendants. The corporation, Robert H. Wyatt, and Walter M. Boyett each fined \$100; Ralph H. Duncan fined \$50. (F. D. C. No. 29127, Sample Nos. 27074-K, 61723-K, 61725-K, 61741-K, 62073-K.)

Information Filed: June 7, 1950, Western District of Kentucky, against Evans Drug Co., Inc., Mayfield, Ky., and Robert H. Wyatt, president, and Walter M. Boyett and Ralph H. Duncan, pharmacists.

INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Kentucky, of quantities of diethylstilbestrol tablets, Dexedrine Sulfate tablets, and sulfadiazine and sodium bicarbonate tablets.

ALLEGED VIOLATION: On or about September 10, 24, and 28, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

The five counts of the information charged violations by the corporation and its president, Robert H. Wyatt. Ralph H. Duncan was joined as a defendant in count 1, charged with making the sale involved in that count, and Walter M. Boyett was joined as a defendant in counts 4 and 5, charged with making the sales involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged diethylstilbestrol tablets and the Dexedrine Sulfate tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), they failed to bear labeling containing directions for use; and, Section

- 502 (f) (2), the sulfadiazine and sodium bicarbonate tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- DISPOSITION: October 23, 1950. Pleas of nolo contendere having been entered on behalf of the corporation and Robert H. Wyatt, the court fined each of these defendants \$100 and dismissed counts 3, 4, and 5 against them. Pleas of nolo contendere having been entered by Walter M. Boyett to counts 4 and 5 and by Ralph H. Duncan to count 1, the former was fined \$100 and the latter \$50.
- 3264. Misbranding of Dexedrine Sulfate tablets, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets. U. S. v. Walter W. Evans and Robert A. Binford (Evans Drug Co.). Pleas of nolo contendere. Each defendant fined \$150. (F. D. C. No. 29124. Sample Nos. 61643-K, 61664-K, 61678-K to 61680-K, incl., 61753-K.)
- INFORMATION FILED: June 7, 1950, Western District of Kentucky, against Walter W. Evans and Robert A. Binford, trading as the Evans Drug Co., a partnership, Fulton, Ky.
- INTERSTATE SHIPMENT: From the States of Pennsylvania, Missouri, and Indiana, into the State of Kentucky, of quantities of Dexedrine Sulfate tablets, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets.
- ALLEGED VIOLATION: On or about September 13, 18, and 24, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of Dexedrine Sulfate tablets, sulfadiazine tablets, thyroid tablets, and diethylstilbestrol tablets to be repackaged and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.
- NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.
 - Further misbranding, Section 502 (f) (2), the repackaged sulfadiazine tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.
- DISPOSITION: October 23, 1950. Walter W. Evans and Robert I. Binford having entered pleas of nolo contendere, the court fined the former \$150 on counts 1, 2, and 3, and the latter \$150 on counts 4, 5, and 6. Counts 4, 5, and 6 against Walter W. Evans and counts 1, 2, and 3 against Robert I. Binford were dismissed.
- 3265. Misbranding of Triple Sulfonamides tablets, Dexedrine Sulfate tablets, diethylstilbestrol tablets, and pentobarbital sodium capsules. U. S. v. Carl E. Neels. Plea of guilty. Fine, \$1,100. (F. D. C. No. 29435. Sample Nos. 60867-K, 60868-K, 60938-K, 60939-K, 60954-K, 60955-K, 60974-K.)
- INFORMATION FILED: July 25, 1950, Eastern District of Missouri, against Carl E. Neels, a pharmacist for Neels Drugs, St. Louis, Mo.
- INTERSTATE SHIPMENT: From the States of Ohio, Pennsylvania, Indiana, and New York, into the State of Missouri, of quantities of Triple Sulfonamides